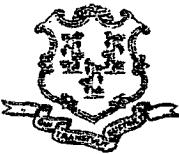


STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH



Raul Pino, M.D., M.P.H.
Commissioner

Ned Lamont
Governor
Susan Bysiewicz
Lt. Governor

Healthcare Quality And Safety Branch

March 4, 2019

Mr. Gary Havican, Administrator
Hospital Of Central Connecticut, The
100 Grand Street
New Britain, CT 06050

Dear Mr. Havican:

Unannounced visits were made to the Hospital Of Central Connecticut that concluded on February 7, 2019 by a representative of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting an investigation with additional information received through February 7, 2019.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which was/were noted during the course of the visits.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice.

The plan of correction is to be submitted to the Department by March 14, 2019

The plan of correction shall include:

- (1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;
- (2) the date each such corrective measure or change by the institution is effective;
- (3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and
- (4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by March 14, 2019 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.



Phone: (860) 509-7400 • Fax: (860) 509-7543

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We do anticipate making any practitioner referrals at this time.

If there are any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,



Heidi Caron, MSN, RN, BC, CLNC
Supervising Nurse Consultant
Facility Licensing and Investigations Section

HAC:mb

Complaint #24790

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The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b)
Administration (2) and/or (i) General (6) and/or (l) Infection Control (1).

1. Based on medical record reviews, review of facility policies and interviews for one of two patients (Patient #1) who had a cardiac arrest in the OR (operating room), the facility failed to ensure staff utilized the overhead peri-operative paging system during an emergency in accordance with facility policy and/or that infection control practices were followed in accordance with facility policy/standard of practice. The findings include:
 - a. Patient #1 was admitted to the hospital on 12/30/18 with a diagnoses of thyrotoxicosis with a goiter and thyroid storm. P#1 had a history of Graves disease. P #1 was assessed as an ASA (American Society of Anesthesiologists) surgical risk "4" (patients with severe systemic disease) and underwent an uncomplicated thyroidectomy under general anesthesia on 1/9/19 by MD #1. Review of the immediate operative report dated 1/9/19 identified a 10cc (cubic centimeters) (minimal) blood loss during the operative procedure. Review of the anesthesia record dated 1/9/19 indicated that P #1 was easily intubated for the procedure and was extubated by CRNA #2 (certified registered nurse anesthetist) uneventfully at 5:39 PM while deeply sedated and breathed spontaneously post extubation. P #1's BP (blood pressure) was 100/50 at the time of extubation. P #1's BP began to slowly increase following extubation (despite the administration of Dilaudid at 5:44PM and at 5:48PM with the BP noted to be 170/80 at 5:48PM. The anesthesia record at 5:49 PM indicated that P #1 was short of breath, nodded yes when asked if he/she was having difficulty breathing, was assessed as having wheezes (by CRNA #1) and 3 puffs of Albuterol (bronchodilator) was administered into P #1's mask without relief. Review of CRNA #2's documentation at 5:51 PM identified that P #1's breathing progressed to slight stridor, was provided breathing support via mask, slight neck swelling was observed and both MD #1 and Anesthesiologist #2 were called to the operating room via phone (not via overhead page). Review of Anesthesiologist #2's note dated 1/9/19 indicated the he/she was called to the operating room at 5:52 PM (4 minutes after breathing difficulty began), and P #1 was stridorous, had swollen oral tissue and, with the use of a glidescope (for visualization) Anesthesiologist #2 had difficulty intubating with an ETT (endotracheal tube). Further review of the Anesthesiologist's #2's note identified that during intubation, P #1's arterial line went flat, P #1 became pulseless and CPR (cardio-pulmonary resuscitation) was initiated at 5:48pm. Review of the operative report dated 1/9/19 by MD #1 (surgeon) noted that the surgical resident called him back to the operating room (OR) and that he was unaware a code had been called in the OR Room. Review of the discharge summary dated 1/19/19 identified that after several minutes during CPR, another assessment was conducted to look at the ETT noted that it was not in the trachea, the outcome was a severe anoxic brain injury and P#1 subsequently expired on 1/19/19. Interviews with RN #1 (Charge) and RN #2 (Circulator) on 1/25/19 at 10:37 AM and 12:02 PM respectively indicated that the cardiac code was not paged on the overhead system. Interview with RN #1 on 1/25/19 at 10:37 AM noted that he/she called the PACU (post

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anesthesia care unit) via phone and asked for assistance because P #1 was "coding". Interview with the Regional Director of Perioperative Services on 1/25/19 at 10:37 AM identified that the "TOA" (overhead perioperative paging system) was the process for requesting immediate assistance on the OR. The facility policy for medical response in the perioperative setting directed to use TOA and announce "Medical Response, Cardiac" and your location.

Subsequent to the event, the facility provided immediate re-education to perioperative staff regarding the use of the TOA system.

- b. A tour of the perioperative area was conducted on 2/6/19 at 8:38 AM. Observations on 2/6/19 of the main OR at 9:02 AM of the cystoscopy room and of OR #2 at 9:04 AM identified a build-up of dust on the horizontal surfaces of electronic monitor screens. Observations on 2/6/19 of the ASU (Ambulatory Surgical Unit) at 9:29 AM noted a build-up of dust on the horizontal surfaces of monitors located in OR's #3, #4 and #5. Interview with the Supervisor of Perioperative Services on 2/6/19 at 9:02 AM indicated that monitor screens should be cleaned as part of room cleaning. The facility policy for surgical areas cleaning identified that daily terminal cleaning included to damp wipe and disinfect all horizontal and vertical surfaces.
- c. A tour of the perioperative area was conducted on 2/6/19 at 8:38 AM. Observations on 2/6/19 in the ASU at 9:41 AM identified the CRNA (certified registered nurse anesthetist) in OR #3 drawing up medications from three medication vials into three separate syringes. The observation further noted that the CRNA would pop off the top to each vial and immediately access each vial without the benefit of first sanitizing the septum of the vial with an alcohol wipe. Interview with Anesthesiologist #2 on 2/6/19 at 9:43 AM indicated that anesthesia staff know that the vial septum should be wiped off with an alcohol wipe prior to access. The facility anesthesia policy for medication management directed to clean the top of the vial with alcohol before drawing medication into the sterile syringe. And/or

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (i) General (6).

- 2. Based on medical record reviews, review of facility policies, review of facility documentation and interviews for one of seven patients reviewed for anesthesia services during a cardiac arrest (Patient #1), the facility failed to ensure that extubation protocols were followed and/or that lung sounds and/or ETT (endotracheal tube) placement were accurately assessed and/or that facility policy for medical response during the cardiac code was followed. The finding includes:
 - a. Patient #1 was admitted to the hospital on 12/30/18 with diagnoses of thyrotoxicosis with goiter and thyroid storm. P#1 had a history of Graves Disease. P #1 was assessed as an ASA surgical risk "4" (patients with severe systemic disease) and underwent an uncomplicated thyroidectomy under general anesthesia on 1/9/19 by MD #1. Review of the immediate operative report dated 1/9/19 identified a 10cc (minimal) blood loss during the operative procedure.

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Review of the anesthesia record dated 1/9/19 indicated that P #1 was easily intubated for the procedure, was extubated by CRNA #2 (certified registered nurse anesthetist) uneventfully at 5:39 PM while deeply sedated and breathed spontaneously post extubation in the absence of the anesthesiologist. P #1's BP (blood pressure) was 100/50 (low range) at the time of extubation. P #1's BP began to slowly increase following extubation (despite the administration of Dilaudid at 5:44PM and at 5:48PM) with the BP noted to be 170/80 at 5:48PM.

Review of the anesthesia record authored by CRNA #2 at 5:49 PM noted that P #1 was short of breath, nodded yes when asked if he/she was having difficulty breathing, was assessed as having wheezes (by CRNA #1) and 3 puffs of Albuterol (bronchodilator) was administered into P #1's mask without relief. Review of CRNA #2's documentation at 5:51 PM identified that P #1's breathing progressed to slight stridor, was provided breathing support via mask, slight neck swelling was observed and both MD #1 and Anesthesiologist #2 were called to the room via phone (not via overhead page).

Review of Anesthesiologist #2's note dated 1/9/19 indicated the he/she was called to the room at 5:52 PM (4 minutes after breathing difficulty began), arrived immediately, P #1 was stridorous, had swollen oral tissue and with the use of a glidescope (for visualization) the patient was difficult to intubate with an ETT (endotracheal tube). Further review of Anesthesiologist #2's note identified that during intubation, P #1's arterial line went flat, P #1 became pulseless and CPR (cardio-pulmonary resuscitation) was initiated at 5:48 PM. Although Anesthesiologist #2 documented that the ETT placement was verified by an anesthesiology team member (CRNA #1), P #1's CO₂ (carbon dioxide) level was 49 at 5:20PM then dropped to 6 at 5:35PM and 3 at 5:45pm (normal CO₂ levels are 35-45), the pulse oximeter kept falling off P #1's finger (therefore unable to adequately monitor oxygen level in the blood/resuscitation effectiveness) and Anesthesiologist #1 taped the ETT to P#1 to free her hands. Review of the documentation by Anesthesiologist #2 identified that she palpated P #1's stomach herself, noted that it felt firm (air entering stomach instead of lungs), removed the ETT and with the glidescope reinserted the ETT (at 6:05 PM). Further review identified that within 7 minutes into the code, P #1 had immediate ROSC (return of spontaneous circulation).

Review of the discharge summary dated 1/19/19 identified that after several minutes during CPR, another assessment was conducted at the ETT which indicated that it was not in the trachea. Further review identified that the outcome was severe anoxic brain injury and P#1 subsequently expired on 1/19/19.

Interview with the Senior VP of Clinical Services for the facility (contracted anesthesia group) on 1/25/19 at 11:00 AM identified that the elevated BP caused increased venous congestion which lead to bleeding. Further interview identified that per protocol, Anesthesiologist #2 should have been in the room at the time P #1 was extubated as P #1 had a "high risk" airway. In addition, the Senior VP further identified that there was a delay in calling Anesthesiologist #2 to the room and CRNA #2 was responsible to ensure that this was done.

Interview with Anesthesiologist #2 on 1/29/19 at 8:35 AM indicated that he/she told the

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CRNA that P #1 was probably stridorous from the beginning and was inaccurately assessed. Anesthesiologist #2 noted that CRNA #1 confirmed ETT placement after P #1 was intubated.

Interview with CRNA #1 on 1/29/19 at 10:05 AM identified that he/she informed Anesthesiologist #2 that he/she heard something but, that it sounded distant (questionable ETT placement). CRNA #1 further indicated that he/she had directed RN #2 to get the "code cart" when P #1 became pulseless.

Interview with Anesthesiologist #1 on 1/29/19 at 10:05 AM identified that in terms of the code, there was a failure to delegate and during the code, someone had to identify themselves as the leader. Further interview identified that Anesthesiologist #1 noted that end title CO2 was the gold standard for determining proper ETT placement.

Interview with Anesthesiologist #5 on 2/6/19 at 1:10 PM indicated factors including effective manual ventilation, symmetrical chest rise and an end-tidal CO2 waveform on the gas analyzer would indicate if the airway was placed correctly.

Interview with MD #2 on 2/5/19 at 2:24 PM identified that, upon review, P #1's airway (ETT) was never in place until it was readjusted because after readjustment, P #1 had immediate ROSC (return of spontaneous circulation).

Review of facility policy for medical response in the perioperative setting identified that the anesthesiologist is the physician in charge of the "Medical Response, Cardiac or Respiratory". The amended anesthesia agreement dated 8/1/13 identified that the anesthesia group will be responsible for the supervision of the post anesthesia care of the patient. Subsequent to the event, all anterior neck surgeries were suspended prior to an internal review. Post review, the facility revised their perioperative Medical Response policy approved on 1/16/19 to include the use of the hospital-wide paging system and code team response followed by staff education. In addition, Anesthesia Staff will be required to complete an advanced airway refresher course.

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The filing of this Plan of Correction does not constitute any admissions to any of the alleged violations set forth in this statement of deficiencies. The Plan of Correction is being filed as evidence of the facility's continued compliance with all applicable laws and the facility's desire to continue to provide quality services. The facility requests that this plan of correction be considered as its allegation of substantial compliance.

ATTACHMENT 1

Prefix ID	Corrective Measure(s) and Follow-up Measures	Completion Date	Responsible Staff by Title
	<p>Prior to survey and immediately following the event, an immediate Plan of Correction (PoC) was put into place to ensure appropriate delivery of anesthesia services. To that end, an interdisciplinary team was organized comprised of Executive Leaders, Anesthesia Leaders, Chief of Surgery, Perioperative Director, Perioperative Managers, Perioperative Clinical Educator, Patient Safety Program Manager and Quality and Safety Coordinator. Key components of this PoC include the following and are discussed in greater detail throughout this response.</p> <ul style="list-style-type: none"> • Education, ongoing training and awareness communications for Anesthesiologists, CRNAs, perioperative staff and providers • Documentation expectations and staff accountability • Policy revision/development • Monitoring and feedback of staff performance expectations <p>Executive, Anesthesia and Perioperative Leadership is engaged and committed to ongoing monitoring of outcomes through the following processes:</p> <ul style="list-style-type: none"> - Monthly review of the plan of correction and audit results at the Performance Improvement Coordinating Council (PICC) and QAPIC meetings beginning January 2019. - Monthly Quality Assessment and Performance Improvement review of Plan of Correction (PoC) and audit results until acceptable results are met beginning January 2019. - As part of the overall QAPI reporting plan the PoC will be reviewed quarterly by the Hospital Board. 		
1.a.	<p>Prior to survey and immediately following this event, an immediate Plan of Correction (PoC) identifying a comprehensive response was implemented. Implementation of this plan began 1/14/2019. To ensure needed input, an interdisciplinary team representing key stakeholders was organized including, hospital executive leadership, executive leaders of anesthesia services, including chief of anesthesia, chief of surgery, nurse executive leaders, nurse perioperative leaders, clinical education and quality and safety. Key components of this PoC include the following:</p> <ol style="list-style-type: none"> 1. The Anesthesia leadership team conducted an internal review of the event circumstances to identify internal process gaps of anesthesia services. Completed 1/14/19. 2. Anesthesia leadership communicated to anesthesiologists and CRNAs that an Anesthesiologist will be present during induction and extubation of emergent and anterior neck surgery cases. Completed 1/14/19. 3. An Executive leadership meeting including Vice President of Medical affairs, Chief of Anesthesia, Chief of Surgery, and Perioperative Administration was conducted to identify action items following review of the event circumstances. Completed 1/17/2019. 4. A 2 week stand down for neck surgeries was enacted during which time a thorough investigation of event circumstances would be undertaken. Initiated 1/17/19. 5. Anesthesiologists, CRNAs, and Perioperative staff were educated to a revision to the policy, Medical Response in the Perioperative Setting. Revision was made regarding overhead announcements of cardiac responses in the OR. Currently these overheads are announced within the perioperative environment using the TOA system. The policy has been revised to also include a facility wide overhead page for OR cardiac response to enhance perioperative code responses. Completed 1/16/2019. 	2/04/19	Chief of Anesthesia, Director Peri-Operative Administration

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	<ul style="list-style-type: none"> a. For cardiac arrests in OR, stat pages will continue to be made to Anesthesia and Charge RN at which time the anesthesiologist will initially assume role of team leader for cardiac response. b. New: OR staff will activate a hospital wide emergency response at which time the hospital Code Team will arrive. Once the Code Team arrives the critical care provider team member will assume the role of team leader for remainder of cardiac response. <p>6. A Mandatory airway management meeting for all anesthesia providers, including anesthesiologists and CRNAs was conducted on 1/30/19. Items reviewed:</p> <ul style="list-style-type: none"> a. Review of the critical event b. Review of hospital/system response c. Anesthetic management of difficult airway d. Airway rescue techniques e. Communication between Anesthesia/peri- op staff and surgery in planning high risk complex cases <ul style="list-style-type: none"> i. Laminated airway algorithm (SHOUT card) readily accessible to anesthesia staff for risks, signs and symptoms of patients at risk for airway emergency. f. Mandatory participation in Difficult Airway Course required for all anesthesiologists and CRNAs by end of calendar year 2019. Proof of Attendance required as evidence of participation. 2019 Course dates and locations provided to Anesthesia providers. <p>7. Daily anesthesia department safety staff huddles were implemented with expectation that all onsite anesthesia staff attend. Discussion items include department communications, concerns of past and upcoming 24 hours including patient concerns, volume/scheduling, equipment concerns and other. Initiated 2/04/19.</p> <p><u>Monitoring Plan:</u> Ongoing monitoring will be conducted of all perioperative emergency response codes (including perioperative mock codes) to ensure appropriate cardiac response notification and established emergency response protocols are followed, including code team arrival, designated code leader, accurate assessment of lung sounds and/or ETT placement.</p>		
1.b.	<p>Because the facility failed to ensure appropriate cleaning practices were consistently followed, the following measures were put into place:</p> <p><u>Corrective Actions:</u></p> <ol style="list-style-type: none"> 1. The Director of Environmental Services ensured all staff assigned to cleaning in the peri-operative environment receive during orientation education on required cleaning practices and frequency of OR computer screens, including dusting of horizontal surfaces. Completed 3/10/19. 2. The Director of Environmental Services reviewed for one week during daily department safety huddles required cleaning practices of OR computer screens including frequency of cleaning. Initiated 3/10/19. <p><u>Monitoring Plan:</u> The Director of Environmental Services will audit 5 OR computer screens per week to ensure dust free surfaces. Audits will continue until 100% compliance is achieved for 8 consecutive weeks.</p>	3/10/19	Director of Environmental Services 

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1.c.	<p>Because for one CRNA, the facility failed to ensure appropriate practices were followed when accessing medication vials, the following measures were put into place:</p> <p>Corrective Actions:</p> <ol style="list-style-type: none"> 1. The Director of Anesthesia communicated to all CRNAs and anesthesiologists the expectation that prior to withdrawing medications from medication vials, the septum of the vial must first be sanitized with an alcohol wipe. Completed 3/09/19. <p>Monitoring Plan:</p> <p>The Director of Anesthesia or designee will conduct 10 observational audits per month to ensure anesthesia staff sanitize medication vial septums with an alcohol wipe prior to accessing. Audits will continue until 100% compliance is achieved for 3 months.</p>	3/09/19	Director, Anesthesia Services 
2.a.	<p>Prior to survey and immediately following this event, an immediate Plan of Correction (PoC) identifying a comprehensive response was implemented. Implementation of this plan began 1/14/2019. To ensure needed input, an interdisciplinary team representing key stakeholders was organized including, hospital executive leadership, executive leaders of anesthesia services, including chief of anesthesia, chief of surgery, nurse executive leaders, nurse perioperative leaders, clinical education and quality and safety. Key components of this PoC include the following:</p> <ol style="list-style-type: none"> 1. The Anesthesia leadership team conducted an internal review of the event circumstances to identify internal process gaps of anesthesia services. Completed 1/14/19. 2. Anesthesia leadership communicated to anesthesiologists and CRNAs that an Anesthesiologist will be present during induction and extubation of emergent and anterior neck surgery cases. Completed 1/14/19. 3. An Executive leadership meeting including Vice President of Medical affairs, Chief of Anesthesia, Chief of Surgery, and Perioperative Administration was conducted to identify action items following review of the event circumstances. Completed 1/17/2019. 4. A 2 week stand down for neck surgeries was enacted during which time a thorough investigation of event circumstances would be undertaken. Initiated 1/17/19. 5. Anesthesiologists, CRNAs, and Perioperative staff were educated to a revision to the policy, Medical Response in the Perioperative Setting. Revision was made regarding overhead announcements of cardiac responses in the OR. Currently these overheads are announced within the perioperative environment using the TOA system. The policy has been revised to also include a facility wide overhead page for OR cardiac response to enhance perioperative code responses. Completed 1/16/2019. <ol style="list-style-type: none"> a. For cardiac arrests in OR, stat pages will continue to be made to Anesthesia and Charge RN at which time the anesthesiologist will initially assume role of team leader for cardiac response. b. New: OR staff will activate a hospital wide emergency response at which time the hospital Code Team will arrive. Once the Code Team arrives the critical care provider team member will assume the role of team leader for remainder of cardiac response. 6. A Mandatory airway management meeting for all anesthesia providers, including anesthesiologists and CRNAs was conducted on 1/30/19. Items reviewed: <ol style="list-style-type: none"> c. Review of the critical event d. Review of hospital/system response e. Anesthetic management of difficult airway f. Airway rescue techniques g. Communication between Anesthesia/peri- op staff and surgery in planning high risk complex cases <ol style="list-style-type: none"> i. Laminated airway algorithm (SHOUT card) readily accessible to anesthesia staff for risks, signs and 	2/04/19	Chief of Anesthesia, Director Peri-Operative Administration 

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	<p style="padding-left: 40px;">symptoms of patients at risk for airway emergency.</p> <p class="list-item-l1">h. Mandatory participation in Difficult Airway Course required for all anesthesiologists and CRNAs by end of calendar year 2019. Proof of Attendance required as evidence of participation. 2019 Course dates and locations provided to Anesthesia providers.</p> <p class="list-item-l1">7. Daily anesthesia department safety staff huddles were implemented with expectation that all onsite anesthesia staff attend. Discussion items include department communications, concerns of past and upcoming 24 hours including patient concerns, volume/scheduling, equipment concerns and other. Initiated 2/04/19.</p> <p><u>Monitoring Plan:</u> Ongoing monitoring will be conducted of all perioperative emergency response codes (including perioperative mock codes) to ensure appropriate cardiac response notification and established emergency response protocols are followed, including code team arrival, designated code leader, accurate assessment of lung sounds and/or ETT placement.</p>		
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